K082356 page 1 of 2

AUG 28 2008

SPECIAL 510(k) SUMMARY

Applicant:

W. L. Gore and Associates, Inc.
1505 North Fourth St.
Flagstaff, AZ 86004

Contact:

Alicia L. Hemphill
Regulatory Affairs Associate
3450 W. Kiltie Lane
Flagstaff, AZ 86001

Phone - (928) 864-4328
Fax – (928) 864-4304

Date Prepared:

Aug 15, 2008

Proprietary Device Name:

GORE Introducer Sheath with Silicone Pinch Valve

Common Name: Introducer Sheath

Classification: 21CFR 870.1340, DYB Class II

Device Predicate:

K032073 GORE Introducer Sheath with Silicone Pinch Valve

Device Description:

This 510(k) is being submitted for a minor modification to the product configuration made to the GORE Introducer Sheath with Silicone Pinch Valve cleared under K032073. The proposed modification that is subject of this 510(k) submission is to offer an additional 18Fr size introducer sheath to the current product line. No other changes are being made to the GORE Introducer Sheath with Silicone Pinch Valve or its packaging as cleared under K032073.

Statement of Intended Use:

The GORE Introducer Sheath with Silicone Pinch Valve is intended for use to facilitate the introduction of catheters and other medical devices into the vasculature and to minimize blood los associated with such introduction.

Note: The intended use of the modified device, as described in its labeling, has not changed as a result of the modification.

Technological Characteristics:

The sole difference between the predicate GORE Introducer Sheath with Silicone Pinch Valve and the GORE Introducer Sheath with Silicone Pinch Valve which is subject of this 510(k) submission is the additional 18Fr device size.

Substantial Equivalence:

A variety of tests, assessments, and comparisons demonstrate that the GORE Introducer Sheath with Silicone Pinch Valve is substantially equivalent to its predicate in terms of design, intended use, principle of operation, and performance attributes.

Differences between the predicate GORE Introducer Sheath device and the proposed GORE Introducer Sheath device with the additional 18Fr device size do not raise any significant issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 28 2008

W. L. Gore & Associates, Inc.
c/o Ms. Alicia Hemphill
Regulatory Affairs
3450 W. Kiltie Lane
Flagstaff, AZ 86001

Re: K082356
GORE Introducer Sheath with Silicone Pinch Valve.
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II (Two)
Product Code: DYB
Dated: August 11, 2008
Received: August 18, 2008

Dear Ms. Hemphill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082356

Device Name: GORE Introducer Sheath with Silicone Pinch Valve

Indications For Use:

The GORE Introducer Sheath with Silicone Pinch Valve is indicated for use to facilitate the introduction of catheters and other medical devices into the vasculature and to minimize blood loss associated with such introduction.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vechinski

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082356